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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,053	09/08/2003	Anna P. Catania	54275.8005.US03	3809

34055 7590 07/20/2006

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EXAMINER	
GUPTA, ANISH	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 07/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/659,053	CATANIA ET AL.	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-42 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-42 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 2-9-04, 10-24-05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The preliminary amendment, filed 6-7-04, is acknowledged. Claims 3, 17, 18, 31, 33, 41 and 42 were amended. Claims 1-42 are pending in this application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,894,028 in view of Borgman (US 4837378).

The claims are drawn to pharmaceutical composition comprising a KPV dimer, first preservative agent, a solvent, an alkalizer, an acrylic acid based polymer, a second preservative agent and a gelatinizing agent.

A pharmaceutical composition for the treatment of psoriatic disorders and contact dermatitis comprising: a) a therapeutically effective amount of a KPV polypeptide (SEQ ID NO: 1) a therapeutically effective amount of a glucocorticoid anti-inflammatory agent wherein the combination of a KPV polypeptide and glucocorticoid anti-inflammatory agent is effective for treatment of psoriatic disorders and contact dermatitis (see claim 1). The KPV polypeptide a KPV monomer of KPV dimer (see claim 2). The Patent claims claims a composition in the form of a gel (see claim 4). The difference between the US patent and the instant claims is that the US patent does not teach the composition claimed that includes preservative agent, a solvent, an alkalizer, an acrylic acid based polymer, a second preservative agent and a gelatinizing agent.

However, Borgman et al. teach formulation, in the form of a gel, for the treatment of dermatitis (see col. 3, lines 20-26). The reference states that gel posses the advantageous properties of including utliziing non-comedogenic, non-acneogenic, and non-irritating ingredients (see col. 21-25). The reference specifically discloses the use of carbopol 940 as the gel forming polymer (see col. 4, lines 53-68 and col. 5, lines 1-2). The composition includes a penetration enhancer that promotes penetration of the active drug into the patients skin or tissue. These include DMSO or propylene glycol (see col. 5, lines 23-31). The composition includes preservatives, such as a mixture of methyl paraben and propyl paraben, in an amount effective for inhibiting growth of microbes such as yeast and molds during storage (see col. 5, lines 33-42). Further, ethylenediaminetetraacetic acid (EDTA) or one of its salts is commonly added to dermatological preparations, and may optionally be incorporated into the compositions of the present invention. EDTA chelates certain metals that may be present in the formulation, which is useful because some patients have adverse reactions to preparations containing metal impurities (see col. 5, lines 44-55). Finally, the final pH value of the formulations of the invention may vary within a physiologically compatible range. Advantageously,

the final pH value is a physiologically compatible, i.e., not harmful to biological tissue, acidic pH value. The pH value is preferably between about 3 and about 6.9, and most preferably between about 4 and 5. Any suitable method of adjusting the pH value of aqueous solutions may be used. Advantageously, sodium hydroxide (NaOH) is added to the composition to bring the final pH value to the desired level. Gel compositions of the invention are more viscous at pH values that approach neutrality than at the more acidic pH values within the preferred range, i.e., viscosity increases as the polymer in the gel is neutralized to a greater degree, e.g., with NaOH (see paragragph bridging col. 5-6). Note that the non-active agent utilized in the reference are identical to those claimed in claim 41-42 of the instant application. Since the US patent claims KPV dimer formulation in the form of gels, it would have been obvious to one of ordinary skill in the art to use the non-active agents disclose in Borgman because of the advantageous properties of including utliziing non-comedogenic, non-acneogenic, and non-irritating ingredients.

3. Claims 1-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6800291 in view of Borgman (US 4837378).

The claims are drawn to pharmaceutical composition comprising a KPV dimer, first preservative agent, a solvent, an alkalizer, an acrylic acid based polymer, a second preservative agent and a gelatinizing agent.

The US patent claims A composition comprising a dimer wherein the dimer comprises a formula $(Cys\text{-}Lys\text{-}Pro\text{-}Val)_2$ (see claim 1). The claims also state that the composition is in the form of a gel (see claim 7). The difference between the US patent and the instant claims is that the US

patent does not teach the composition claimed that includes preservative agent, a solvent, an alkalizer, an acrylic acid based polymer, a second preservative agent and a gelatinizing agent.

However, Borgman et al. teach formulation, in the form of a gel, for the treatment of dermatitis (see col. 3, lines 20-26). The reference states that gel posses the advantageous properties of including utliziing non-comedogenic, non-acneogenic, and non-irritating ingredients (see col. 21-25). The reference specifically discloses the use of carbopol 940 as the gel forming polymer (see col. 4, lines 53-68 and col. 5, lines 1-2). The composition includes a penetration enhancer that promotes penetration of the active drug into the patients skin or tissue. These include DMSO or propylene glycol (see col. 5, lines 23-31). The composition includes preservatives, such as a mixture of methyl paraben and propyl paraben, in an amount effective for inhibiting growth of microbes such as yeast and molds during storage (see col. 5, lines 33-42). Further, ethylenediaminetetraacetic acid (EDTA) or one of its salts is commonly added to dermatological preparations, and may optionally be incorporated into the compositions of the present invention. EDTA chelates certain metals that may be present in the formulation, which is useful because some patients have adverse reactions to preparations containing metal impurities (see col. 5, lines 44-55). Finally, the final pH value of the formulations of the invention may vary within a physiologically compatible range. Advantageously, the final pH value is a physiologically compatible, i.e., not harmful to biological tissue, acidic pH value. The pH value is preferably between about 3 and about 6.9, and most preferably between about 4 and 5. Any suitable method of adjusting the pH value of aqueous solutions may be used. Advantageously, sodium hydroxide (NaOH) is added to the composition to bring the final pH value to the desired level. Gel compositions of the invention are more viscous at pH values that approach neutrality than at the more acidic pH values within the preferred range, i.e., viscosity increases as the polymer in the gel is neutralized to a greater degree, e.g., with NaOH (see paragragph bridging col.

5-6). Note that the non-active agent utilized in the reference are identical to those claimed in claim 41-42 of the instant application. Since the US patent claims KPV dimer formulation in the form of gels, it would have been obvious to one of ordinary skill in the art to use the non-active agents disclose in Borgman because of the advantageous properties of including utliziing non-comedogenic, non-acneogenic, and non-irritating ingredients.

4. Claims 1-42 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,887,846in view of Borgman (US 4837378).

The claims are drawn to pharmaceutical composition comprising a KPV dimer, first preservative agent, a solvent, an alkalizer, an acrylic acid based polymer, a second preservative agent and a gelatinizing agent.

The US patent claims a method for reducing the viability or method for killing microbes comprising exposing the microbes to an antimicrobial agent selected from the group consisting of KPV (SEQ ID NO: 1), MEHFRWG (SEQ ID NO: 2), and HFRWGKPV (SEQ ID NO: 3) and dimers thereof (see claim 1). The difference between the US patent and the instant claims is that the US patent does not teach the composition claimed that includes preservative agent, a solvent, an alkalizer, an acrylic acid based polymer, a second preservative agent and a gelatinizing agent.

However, Borgman et al. teach formulation, in the form of a gel, for the treatment of dermatitis (see col. 3, lines 20-26). The reference states that gel posses the advantageous properties of including utliziing non-comedogenic, non-acneogenic, and non-irritating ingredients (see col. 21-25). The reference specifically discloses the use of carbopol 940 as the gel forming polymer (see col. 4, lines 53-68 and col. 5, lines 1-2). The composition includes a penetration enhancer that promotes

penetration of the active drug into the patients skin or tissue. These include DMSO or propylene glycol (see col. 5, lines 23-31). The composition includes preservatives, such as a mixture of methyl paraben and propyl paraben, in an amount effective for inhibiting growth of microbes such as yeast and molds during storage (see col. 5, lines 33-42). Further, ethylenediaminetetraacetic acid (EDTA) or one of its salts is commonly added to dermatological preparations, and may optionally be incorporated into the compositions of the present invention. EDTA chelates certain metals that may be present in the formulation, which is useful because some patients have adverse reactions to preparations containing metal impurities (see col. 5, lines 44-55). Finally, the final pH value of the formulations of the invention may vary within a physiologically compatible range. Advantageously, the final pH value is a physiologically compatible, i.e., not harmful to biological tissue, acidic pH value. The pH value is preferably between about 3 and about 6.9, and most preferably between about 4 and 5. Any suitable method of adjusting the pH value of aqueous solutions may be used. Advantageously, sodium hydroxide (NaOH) is added to the composition to bring the final pH value to the desired level. Gel compositions of the invention are more viscous at pH values that approach neutrality than at the more acidic pH values within the preferred range, i.e., viscosity increases as the polymer in the gel is neutralized to a greater degree, e.g., with NaOH (see paragragph bridging col. 5-6). Note that the non-active agent utilized in the reference are identical to those claimed in claim 41-42 of the instant application. Since the US patent claims KPV dimer formulation in the form of gels, it would have been obvious to one of ordinary skill in the art to use the non-active agents disclose in Borgman because of the advantageous properties of including utliziing non-comedogenic, non-acneogenic, and non-irritating ingredients. One would be motivated to practice the claimed method of US Patent by making a formulation that contains the carrier of Borgman because the formulation could be used topically to combat microbes on skin and tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.

6/8/50

Anish Gupta
Patent Examiner